DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier Ramona Oliver

[Docket No. 99N–1075]

Public Health Impact of Vibrio Parahaemolyticus in Raw Molluscan Shellfish; Draft Risk Assessment Document; Availability; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until July 18, 2001, the comment period on its draft risk assessment on the relationship between *Vibrio parahaemolyticus* in raw molluscan shellfish and human health (66 FR 5517, January 19, 2001). Interested persons were initially given until March 20, 2001, with an extension to May 21, 2001 (66 FR 13546, March 6, 2001), to comment on the draft risk assessment. This reopening of the comment period is in response to a request from the National Fisheries Institute (NFI) on behalf of the Gulf Oyster Industry Council, the Pacific Coast Shellfish Growers Association, and the Molluscan Shellfish Institute. The agency does not anticipate further extensions of the comment period for this draft risk assessment.

DATES: Submit written comments by July 18, 2001.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Two copies of comments are to be submitted, except that individuals may submit one copy. Comments must be identified with the docket number found in brackets in the heading of this document. Received comments may be reviewed at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Sherri B. Dennis, Risk Assessment Coordinator, Center for Food Safety and Applied Nutrition (HFS–32), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–260–3984, FAX 202–260–9653, e-mail: sdennis@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 19, 2001 (66 FR 5517), FDA announced the availability of a draft risk assessment on the relationship between *Vibrio parahaemolyticus* in raw molluscan shellfish and human health. Comments were sought on the technical aspects of the draft risk assessment in the following areas: (1) The assumptions made, (2) the modeling technique, (3) the data used, and (4) the transparency of the draft risk assessment document. Interested persons were given until March 20, 2001, to comment on the draft risk assessment. In the **Federal Register** of March 6, 2001, FDA extended the comment period to May 21, 2001 (66 FR 13546), because a public meeting to receive comments on the document was scheduled for March 20, 2001 (March 6, 2001, 66 FR 13544), the same day the comment period closed. The NFI, on behalf of the Gulf Oyster Industry Council, the Pacific Coast Shellfish Growers Association, and the Molluscan Shellfish Institute, has requested a second extension of the comment period to allow additional time to review, analyze, and constructively respond to the draft risk assessment. The extended comment period closed on May 21, 2001. FDA, in response to the NFI request, is reopening the comment period until July 18, 2001. The agency does not anticipate further extensions of the comment period for this draft risk assessment.

You must submit written comments to the Dockets Management Branch (address above) by July 18, 2001, in order for those comments to be considered.

A printed copy of the draft risk assessment and/or a CD–ROM of the risk assessment model may be requested by faxing your name and mailing address with the names of the documents you are requesting to the CFSAN Outreach and Information Center at 1–877–366–3322. The documents may be reviewed at the Dockets Management Branch at the address and hours noted above. The draft risk assessment is also available electronically at www.cfsan.fda.gov, www.foodsafety.gov, and www.foodriskclearinghouse.umd.edu.

Dated: 6/12/01
June 12, 2001.

Margaret M. Dotzel,
Associate Commissioner for Policy.

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

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